UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
WHITE PLAINS COURTHOUSE

Jesse Sheiner, individually and on behalf of all others similarly situated, Plaintiff, - against - Supervalu Inc., Defendant	7:22-cv-10262-NSR First Amended Class Action Complaint Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Supervalu Inc. ("Defendant") manufactures adhesive patches promising to deliver 4% lidocaine under the Equaline brand ("Product").

2. The front label representations include "maximum strength," "lidocaine patch," "topical anesthetic," "4% lidocaine," "desensitize aggravated nerves," "for temporary relief of pain [to] back, neck, shoulders, knees [and] elbows," "up to 8 hours of relief," "Fragrance Free," and "compare to Salonpas Lidocaine Patch active ingredient*," with a picture of a body with a patch applied to the lower back.

I. LIDOCAINE BACKGROUND

3. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.

4. Doctors discovered that lidocaine patches are effective in treating general neuropathic pain like muscle and spinal aches and began prescribing the patches off-label.

5. A 2012 study found that over 82% of the usage of prescription lidocaine patches were off-label.

6. As the use of lidocaine patches increased, national brands such as Salonpas and Aspercreme spent significant amounts of money to advertise their over-the-counter ("OTC") patches as equivalent to those available only with a prescription.

7. In 1983, the Food and Drug Administration ("FDA") issued requirements for the labeling, ingredients, uses, and doses of external analgesic products, allowing the use of lidocaine at 4% in the form of an ointment.

8. The first lidocaine patch was approved in 1999 to help reduce pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles.

9. In 2003, the FDA began review of OTC patches to determine the safe and effective concentration of lidocaine in this format.

10. In 2013, the FDA concluded that lidocaine patches were not "generally recognized

as safe and effective" for OTC use because there was insufficient information about how often the plaster or poultice needed to be changed.

II. PRODUCT FAILS TO DELIVER LIDOCAINE IN PROMISED WAY DUE TO ADHESION DEFECTS

A. How Lidocaine Patches Work

11. Lidocaine patches use transdermal/topical delivery systems ("TDS"), which have three main parts: (1) an outer protective backing membrane, (2) a drug-in-adhesive layer, and (3) a release liner that controls the rate and extent of drug administration.

12. Since the FDA did not contemplate the delivery of lidocaine in patch form, their strength cannot be evaluated based on the previously issued guidance.

13. Manufacturers of lidocaine patches like Defendant attempt to meet the FDA's 4% benchmark based on the mass of drug relative to the mass of the adhesive per patch.

14. However, the amount of lidocaine contained in, or delivered by, a lidocaine patch cannot be determined based on the arbitrary measure of a patch's drug-to-adhesive ratio.

15. This allows Defendant to alter the total mass of lidocaine in the Product by adjusting the thickness of back membrane of the patch without changing its dimensions.

16. The result is that purchasers and doctors are misled by the Product's drug-to-adhesive ratio, because they expect the percentage of an active ingredient has a direct correlation to the quantity, or efficacy, of that ingredient within the delivery mechanism.

B. Adhesion Failure Defects

17. Since adequate adhesion is critical to delivery in the form of a patch, any lifting or detaching while walking, sleeping or exercising will compromise dosing.

18. The FDA Adverse Events Reporting System ("AERS") revealed that approximately 70% of consumer complaints about such products, including upon information and belief,

Defendant's Product, relate to their poor adhesion.

19. The FDA concluded that because the patches systemically fail to adhere to the body, they cannot provide the claimed pain relief.

20. This is in line with complaints made by purchasers of the Product to Defendant about its lack of adhesion abilities, through its online website, telephone, and other methods.

21. A January 2021 peer-reviewed study by the Journal of Pain Research analyzed store brand or private label lidocaine patches, substantially similar and/or identical to Defendant's, and concluded that none of them exceeded ninety percent adhesion within the twelve-hour testing period.

22. Rather, their average adhesion after twelve hours was less than forty percent.

23. This was based on a scale where zero reflected complete detachment and fifty percent meant half the patch lifted off the skin but did not fully detach.

24. These findings understated the poor adhesion qualities of private label lidocaine patches, because study participants were required to remain sedentary during the time the patches were applied, whereas typical users will be walking, exercising, sleeping and otherwise attempting to function normally.

25. Although the study tested generic lidocaine patches, a comparison between the samples analyzed and Defendant's Product reveals they both use the same defective adhesion technology, which has not undergone the rigorous FDA approval process.

26. Though other companies have innovated their technology based on clinical studies to ensure their lidocaine patches are sufficiently flexible to adhere to a user's body during walking, sleeping, exercising and other everyday activity, upon information and belief, Defendant has not.

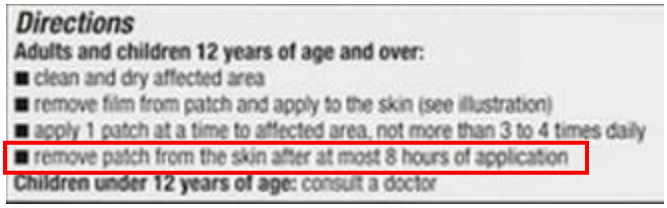
27. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical

delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."

28. Since the Product cannot adhere to a person's skin throughout the promised time period, it cannot deliver the active anesthetic ingredient of lidocaine during that time.

29. When consumers see the promise of "up to 8 hours of relief" by "desensitize[ing] aggravated nerves" to provide "temporary relief of pain [to] back, neck, shoulders, knees [and] elbows," they will expect the Product will adhere to their bodies for no less than eight hours.

30. The Directions on the back-panel Drug Facts confirm the Product will adhere for eight hours because it instructs users to "remove patch from the skin after at most 8 hours of application."


Directions
Adults and children 12 years of age and over:
- clean and dry affected area
- remove film from patch and apply to the skin (see illustration)
- apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- remove patch from the skin after at most 8 hours of application

Children under 12 years of age: consult a doctor

31. However, the Product cannot adhere for any time even approaching eight hours, which renders the Directions misleading, because it assumes it will not have detached by then.

32. Studies have shown the Product is unable to adhere to the skin for more than four hours, often peeling off within minutes of light activity, nowhere near the eight-hour usage time indicated.

33. This inability to adequately adhere during normal use renders the adhesion claims misleading due to the significant disparity between what is promised and what is delivered.

III. MAXIMUM STRENGTH CLAIM IS MISLEADING

34. The representation of "maximum strength" and "4% lidocaine" is misleading for multiple reasons.

35. First, prescription lidocaine patches exist on the market that deliver greater amounts of lidocaine to the user.

36. This includes patches with 5% and 1.8% lidocaine, which utilize advanced technology to maximize bioavailability, so even the 1.8% patch will result in greater amounts of lidocaine being absorbed by the body.

37. These patches rely on next-generation adhesive mechanisms that allow them to remain affixed to the wearer's body for at least twelve hours under normal conditions.[1]

38. Second, the FDA cautioned manufacturers of OTC analgesic products against making "maximum strength" claims because higher strength and greater potency versions of such items were available with a prescription.

39. Third, the FDA knew other more concentrated and potent similar products could appear in proximity to those represented as "maximum strength" on store shelves.

40. The result would be that consumers would be misled when other companies labeled their products as "regular strength," even though both had the same amount of medication and/or active ingredients.

41. Fourth, given that the Product is explicitly compared to Salonpas on its front label, "maximum strength" is misleading because the Equaline product contains roughly forty percent less lidocaine, even though they have similar or identical dimensions.

42. Fifth, numerous studies and reports revealed that users of adhesive lidocaine patches using the same technology used by the Product regularly peel off a user's skin within three to four hours, and sometimes minutes, after being applied.

[1] In studies, this technology maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

43. Since, according to the FDA, the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch" delivered to the target area, these adhesion deficiencies cause the delivery and absorption of lidocaine to be greatly reduced.

44. This inability to adhere for anywhere close to eight hours means the Product cannot deliver the "maximum strength" amount of lidocaine.

IV. DESENSITIZING CLAIMS

45. The Product's promise to "desensitize aggravated nerves" is misleading because it implies its use will completely block and numb nerves and pain receptors, eliminate responses to painful stimuli, and treat neuropathic and musculoskeletal pain, including back and spinal pain.

46. The FDA determined that statements about desensitizing nerves were misleading in the context of these transdermal patch delivery systems.

47. This is because consumers, including Plaintiff, associate such statements with medical treatments requiring a prescription and FDA approval.

48. However, the Product is available without a prescription and has not been approved by the FDA.

49. The front label promise to "desensitize aggravated nerves" is inconsistent and contradictory with its limited approval "[f]or temporary relief of pain," indicated in the "Uses" section of the Drug Facts and on the front label.

Jurisdiction and Venue

50. Jurisdiction is based on the Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

51. The aggregate amount in controversy exceeds $5 million, including any statutory and

punitive damages, exclusive of interest and costs.

52. Plaintiff is a citizen of New York.

53. Defendant is a Delaware corporation with a principal place of business in Minnesota.

54. The members of the class Plaintiff seeks to represent are more than 100, because the Product has been sold with the representations described here for several years, in thousands of locations, including drug stores, convenience stores, grocery stores, big box stores, warehouse club stores, specialty grocers and/or online in the States covered by Plaintiff's proposed classes.

55. Venue is in this District with assignment to the White Plains Courthouse because a substantial part of the events or omissions giving rise to these claims occurred in Sullivan County, including Plaintiff's purchase and/or use of the Product and awareness and/or experiences of and with the issues described here.

Parties

56. Plaintiff Jesse Sheiner is a citizen of Pittston, New York, Sullivan County.

57. Defendant Supervalu Inc. is a Delaware corporation with a principal place of business in Eden Prairie, Minnesota, Hennepin County.

58. Supervalu was a chain of grocery stores throughout the upper Midwest for many years.

59. While Supervalu sold leading national brands, they also sold a large number of OTC products under one of their private label brands, Equaline.

60. Private label products are made by third-party manufacturers and sold under the name of the retailer, or its sub-brands.

61. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.

62. Products under the Equaline brand have an industry-wide reputation for quality and value.

63. In releasing products under the Equaline brand, Defendant's foremost criteria was high-quality equal to or better than the national brands.

64. Defendant was and is able to get national brands to produce its private label items due its loyal customer base, history of high-quality items and tough negotiating.

65. That Equaline branded products met this high bar was proven by focus groups, which rated them above the name brand equivalents.

66. Private label products generate higher profits because national brands spend significantly more on marketing, contributing to their higher prices.

67. A survey by The Nielsen Co. "found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good."

68. Private label products under the Equaline brand benefit by their association with consumers' appreciation and awareness of the Supervalu brand as a whole, which persists even though it became a fully owned subsidiary of United Natural Foods, Inc. ("UNFI") within the past several years.

69. The development of private label items is a growth area for UNFI, as it selects only top suppliers to develop and produce Equaline products.

70. As a result of the false and misleading representations, the Product are sold at a premium price, approximately no less than no less than $9.79 per box of six patches, excluding tax and sales, higher than similar Product, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

71. Plaintiff purchased the Product at locations including Walmart, Walgreens, and/or CVS throughout Sullivan and Orange Counties, among other places, between June 2020 and November 2022, or among other times.

72. Plaintiff purchased the Product to provide pain relief to his neck, back, elbows and shoulders.

73. Plaintiff saw the Product was labeled and marketed as "maximum strength" and capable of delivering 4% lidocaine for "up to 8 hours," and would "desensitize aggravated nerves" and provide at least "temporary relief" to the areas indicated.

74. Plaintiff believed and expected the Product would reliably adhere to his body to deliver 4% lidocaine for not less than eight hours, that they were the maximum strength available, would relieve pain, deliver pain relief through desensitizing aggravated nerves, because that is what the representations and omissions said and implied.

75. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging, hang tags, and/or images on the Product, on the labeling, statements, omissions, claims, statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.

76. However, the Product did not reliably adhere to Plaintiff's body for anywhere close to eight hours, which prevented it from providing even temporary pain relief.

77. Plaintiff bought the Product at or exceeding the above-referenced price.

78. Plaintiff paid more for the Product than he would have had he known the representations and omissions were false and misleading, or would not have purchased it.

79. The value of the Product that Plaintiff purchased was materially less than its value

as represented by Defendant.

80. Plaintiff chose between Defendant's Product and similarly represented yet truthful products which did not misrepresent their attributes, features, and/or components.

Class Allegations

81. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

> **New York Class:** All persons in the State of New York who purchased the Product during the statutes of limitations for each cause of action alleged; and
>
> **Consumer Fraud Multi-State Class**: All persons in the States of West Virginia, Montana, Wyoming, Idaho, Alaska, Kansas, Nebraska, North Dakota, Iowa, Mississippi, Arkansas, and Utah who purchased the Product during the statutes of limitations for each cause of action alleged.

82. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

83. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

84. Plaintiff is an adequate representative because his interests do not conflict with other members.

85. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

86. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

87. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

New York General Business Law ("GBL") §§ 349 and 350

88. Plaintiff incorporates by reference all preceding paragraphs.

89. Plaintiff incorporates by reference all preceding paragraphs.

90. Plaintiff believed the Product would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

91. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

92. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts
(Consumer Fraud Multi-State Class)

93. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.

94. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.

95. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

96. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

97. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

98. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.

99. Defendant's representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

100. Defendant's representations affirmed and promised that the Product would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

101. Defendant described the Product so Plaintiff believed that they would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves, which became part of the basis of the bargain that it would conform to its affirmations and promises.

102. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

103. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high-quality Equaline brand.

104. Plaintiff recently became aware of Defendant's breach of the Product's warranties.

105. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Product's warranties.

106. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums.

107. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.

108. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because they were marketed as if they would reliably adhere and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

109. The Product was not merchantable because Defendant had reason to know the particular purpose for which it was bought by Plaintiff, because he expected it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain, and he relied on Defendant's skill and judgment to select or furnish such a suitable product.

Fraud

110. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it would not adhere for anywhere close to the hours indicated, rendering the "maximum strength" claim false, and was unable to desensitize nerves and numb pain.

111. Defendant is part of one of the largest international conglomerates selling consumer packaged goods, with immense resources and the ability to ensure the products it sold were represented truthfully, yet willingly failed to do so.

112. Defendant misrepresented and/or omitted the attributes and qualities of the Product,

that it provided maximum strength lidocaine in the percentage indicated, to the areas referenced, and for the time period promised.

113. Moreover, the records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive knowledge of the falsity and deception, through statements and omissions.

114. Defendant knew of the issues described here yet did not address them.

115. Defendant's fraudulent intent is evinced by its knowledge that the Product was not consistent with its representations.

Unjust Enrichment

116. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
2. Awarding monetary, statutory and/or punitive damages and interest;
3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and
4. Other and further relief as the Court deems just and proper.

Dated: May 11, 2023

Respectfully submitted,

/s/Spencer Sheehan

Sheehan & Associates, P.C.
Spencer Sheehan
60 Cuttermill Rd Ste 412
Great Neck NY 11021
(516) 268-7080
spencer@spencersheehan.com